

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D 13 DEC 2004

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Applicant's or agent's file reference 237940	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. CT/AU2003/000716	International Filing Date (day/month/year) 6 June 2003	Priority Date (day/month/year) 7 June 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C07C 43/205, 49/84, 65/24, 309/60, 309/75, 309/47, 69/94, 57/50, 205/59, 323/43, 215/50, 219/22, 69/76, 211/57, 43/23, 43/225, 255/37, 65/28; C07D 319/22; A61K 31/075, 31/12, 31/185, 31/192, 31/205, 31/216, 31/255, 31/277, 31/357; A61P 25/00, 29/00, 31/00, 35/00, 37/00, 43/00		
Applicant CORTICAL PTY LTD et al		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input checked="" type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input checked="" type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 7 January 2004	Date of completion of the report 3 December 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer CHRISTINE BREMERS Telephone No. (02) 6283 2313

Basis of the report

With regard to the elements of the international application:*

☒ the international application as originally filed.☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished4. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/fig.5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/000716

I. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: 1-40 (all in part).

because:

☐ the said international application, or the said claims Nos. require an international preliminary examination (*specify*):

relate to the following subject matter which does not

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☒ said claims Nos. 1-40 are so broadly drafted such that a complete search was not economically feasible. The search was therefore limited substantially to the examples and the compounds as named in claim 41. The cited documents are only a representative sample of the citations that were found.

☐ no international search report has been established for said claim Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

T/AU2003/000716

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Statement

Novelty (N)	Claims	YES
	Claims 1-41	NO
Inventive step (IS)	Claims	YES
	Claims 1-41	NO
Industrial applicability (IA)	Claims 1-41	YES
	Claims	NO

Citations and explanations (Rule 70.7)

Novelty and Inventive Step

- D1 NL 6809942 (SYNTEX CORPORATION) 14 January 1970
D2 US 3562336 (NELSON, P H et al) 9 February 1971
D3 DE 2051012 (SYNTEX CORP) 20 April 1972
D4 DE 2258349 (SANDOZ AG) 7 June 1973
D5 DE 2329298 (BOTTU S.A.) 20 December 1973
D6 DT 2442305 (BEECHAM GROUP LTD) 13 March 1975
D7 US 3904682 (FRIED, J H et al) 9 September 1975
D8 US 3935273 (FRIED, J H et al) 27 January 1976
D9 NL 7512107 (SYNTEX CORPORATION) 30 January 1976
D10 US 3958012 (FRIED, J H et al) 18 May 1976
D11 US 3969415 (GALANTAY, E E) 13 July 1976
D12 US 3978124 (FRIED, J H et al) 31 August 1976
D13 US 3994968 (ALVAREZ, F S) 30 November 1976
D14 US 3998966 (FRIED, J H et al) 21 December 1976
D15 US 4009197 (FRIED, J H et al) 22 February 1977
D16 JP 52-133962 (GRELAN PHARMACEUT CO LTD) 9 November 1977
D17 PATENT ABSTRACTS OF JAPAN, JP 62-103074 (HAMARI YAKUHI KOGYO KK) 13 May 1987
D18 JP 63-203631 (NIPPON KAYAKU CO LTD) 23 August 1988
D19 EP 279466 B1 (WARNER-LAMBERT COMPANY) 24 August 1988
D20 EP 284359 B1 (TAKEDA CHEMICAL INDUSTRIES, LTD) 28 September 1988
D21 EP 286944 B1 (ENICHEM SYNTHESIS S.P.A.) 19 October 1988
D22 EP 301813 B1 (AMERICAN HOME PRODUCTS CORPORATION) 1 February 1989
D23 US 4910208 (MISRA, R N) 20 March 1990
D24 EP 372385 A2 (F. HOFFMANN-LA ROCHE AG) 13 June 1990
D25 WO 1991/08744 A1 (ABBOTT LABORATORIES) 27 June 1991
D26 US 5084575 A (KREFT III, A F et al) 28 January 1992
D27 US 5208344 A (KREFT III, A F et al) 4 May 1993
D28 WO 1996/04267 A1 (LABORATORIOS MENARINI S.A.) 15 February 1996
D29 WO 1997/31006 A1 (GLYCOMED INCORPORATED) 28 August 1997
D30 WO 1997/30992 A1 (BRISTOL-MYERS SQUIBB COMPANY) 28 August 1997

Continued in Supplemental Sheet

II. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The description at pages 71-72 is not clear because the substituent at position 2 is named as dodecanyl of compound 9) in example 9. However the substituent appears to have 20 carbons and may therefore be eicosanyl. This is supported by the use of the reagent eicosanol as indicated on page 72 line 1. See item 2.

Claims 18 and 41 are not fully supported by the description because the named compound dodecanyl-6-hydroxy-2-phthoate appears in both claims but does not concur with the examples. See item 1.

The description at page 52 line 7 is not clear in its reference to Figure 3 rather than Figure 4.

The description is not clear. Figure 3, page 13 line 2, page 98 line 14 indicate that the compound is a 3-sulphonic acid. However, page 94 line 4-6, page 96 lines 4-5, page 97 line 4 and Table 2, page 98 lines 4-6 and 29-31, page 100 Table 4 indicate that the compound is a 2-sulphonic acid.

The description is not clear in terms of the first five results in Table 5 page 102.

The description is not clear because there is no Figure 7 in Figures 1-13.

Claim 4 is not clear because

- (a) The first definition on page 117 line 25 is incorrectly written and
- (b) At page 117 lines 27-28 there is no antecedent in claim 1 for R_2 is $(CR_{10}R_{10'})_mSO_3H$, $(CR_{10}-R_{10'})_mSO_3C_{1-20}alkyl$ or $(CR_{10}R_{10'})_mC_{2-20}alkenyl$.

Claim 17 is not clear because there is no antecedent in claim 1 for

- (a) $(CH_2)_mR_{110}$ where R_{110} is $C_{1-3}alkyl$ and
- (b) R_{107} is hydroxy or cyano.

Claims 31-40 are not clear because "q" is not defined.

Claim 41 is not fully supported by the description because compound 22 is not a compound of the invention. R_{102} cannot be H or $R_{106}Y$ cannot be H.

Supplemental Box

to be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

- 31 EP 0818453 B1 (ELI LILLY AND COMPANY) 14 January 1998
32 US 6420375 B1 (&WO 98/37070 A1) (TAKEDA CHEMICAL INDUSTRIES, LTD) 27 August 1998)
33 WO 1999/01768 A1 (NYCOMED AMERSHAM PLC) 14 January 1999
34 ES 2150848 A1 (LABORATORIOS MENARINI, S.A.) 1 December 2000
35 WO 2001/44172 A1 (AXYS PHARMACEUTICALS, INC.) 21 June 2001

36 Bosca, F et al, Photochemistry and Photobiology (2000), vol 71 no 2, 173-177

37 Prabhakar, C et al, " Bioorganic & Medicinal Chemistry Letters (1998), vol 8 no 19, 2725-2730

38 Bosca, F et al, Journal of Photochemistry and Photobiology A: Chemistry (1990), vol 54 no 1, 131-134

39 Hiyama, T et al, Bulletin of the Chemical Society of Japan (1990) vol 63 no 2, 640-2

40 Harusawa, S et al, Synthetic Communications (1984), vol 14 no 14, 1365-1371

41 Ray, J E et al, Journal of Chromatography (1984) vol 336 no 1, 234-238

42 Cavrini, V et al, Farmaco, Edizione Scientifica (1982) vol 37 no 3, 171-178

43 Goudie, A C et al, Journal of Medicinal Chemistry (1978) vol 21 no 12, 1260-1264

44 US 5268458 A (SPRINGER, H) 7 December 1993

45 JP 01076063 (DAINICHISEIKA COLOR AND CHEMICALS MFG. CO.) 22 March 1989

46 EP 123543 (MERCK FROSST CANADA, INC.) 31 October 1984

47 STN FILE CA Abstract No. 91:91390

48 STN FILE CA Abstract No. 89:6137

49 STN FILE CA Abstract No. 77:114208

50 STN FILE CA Abstract No. 71:81118

51 STN FILE CA Abstract No. 67:79969

52 STN FILE CA Abstract No. 64:3950

53 STN FILE CA Abstract No. 57:10708

54 STN FILE CA Abstract No. 51:17182

These documents were cited in the ISR.

The above documents at the locations specified in the ISR disclose compounds, compositions and/or methods that fall within the scope of claims 1-41. Therefore claims 1-41 are not novel and not inventive in light of the above documents.

note that the cited documents are only a representative sample of the citations that were found.

Industrial Applicability

Claims 1-41 are directed to inhibiting cytokine or biological activity of macrophage migration inhibitory factor (MIF) and therefore satisfy the criteria for industrial applicability.